



Mary B. Matterer
302.888.6960
mmatterer@morrisjames.com

July 27, 2012

BY FACSIMILE AND E-FILING

The Honorable Joel Schneider
United States Magistrate Judge
District of New Jersey
Mitchell H. Cohen Building & U.S. Courthouse
4th & Cooper Streets, Room 1050
Camden, NJ 08101

Re: *Sciele Pharma, Inc., et al. v. Lupin Ltd., et al.*,
C.A. No. 09-037 (RBK) (JS)

Shionogi Pharma, Inc., et al. v. Mylan Inc, et al.,
C.A. No. 10-135 (RBK) (JS)

Your Honor:

This firm along with McGuireWoods LLP represents Mylan Inc. and Mylan Pharmaceuticals Inc. (collectively, "Mylan") in the above-referenced, consolidated actions. We write in response to Shionogi's letter dated July 20, 2012 ("Shionogi's July 20 letter") (D.I. 506),¹ addressing the issue of Mylan's production of additional product samples.

At the recent discovery hearing, Your Honor astutely observed that Shionogi's true motive in seeking an immediate production of additional samples upon their manufacture is simply to obtain advance notice of Mylan's plans, if any, to launch its ANDA products. This is not about Shionogi being deprived of discovery. It is not about Mylan's compliance with the discovery rules. And, it is not about prejudice to Shionogi. Shionogi does not dispute these points but argues instead that its motive is irrelevant. We disagree. Although Shionogi's motive may not bear on the analysis of the relevant legal issues, it certainly raises questions about the legitimacy of its request. To be clear, Shionogi's request is improper and is utterly void of legal support. Respectfully, there is no discovery dispute for the Court to resolve, and any Order granting Shionogi's requested relief would be premature and advisory.

Aside from insisting on the production of a settlement agreement to which Shionogi is not entitled, Shionogi has yet to accuse Mylan of failing to comply with its discovery obligations. Any such accusations would be baseless. Throughout this lawsuit, Mylan has consistently met its obligations, and, at the discovery hearing, Mylan again reaffirmed its commitment to comply with its discovery obligations. Furthermore, Mylan acknowledged the Court's Order to Lupin to produce the requested samples and agreed to produce additional

¹ Unless otherwise noted, record citations refer to the docket in Civil Action No. 09-037.

The Honorable Joel Schneider
July 27, 2012
Page 2

Morris James LLP

samples in the event Mylan launches its products. (7/13/2012 Tr. at 72:2-75:7.) That should have resolved any legitimate concerns Shionogi may have. Instead, Shionogi persists in asking the Court to require Mylan to produce the requested samples immediately upon their manufacture in the event Mylan manufactures any more tablets. Practical difficulties aside,² the overarching problem with Shionogi's request is that it seeks judicial action to resolve an issue that has yet to arise.

What Shionogi seems to ignore and has failed to address is the fact that Shionogi has yet to serve a request for the newly-requested samples that complies with the simple requirements of Rule 34 of the Federal Rules of Civil Procedure. Shionogi's position that its present request comes within the previous request and the duty to supplement under Rule 26(e)(1)(A) misapprehends both the nature of the original request and the duty to supplement.

As Shionogi noted in its June 29, 2012, letter to the Court, its Request No. 29 states as follows:

29. Samples of Mylan's ANDA products as well as the materials that make up Mylan's ANDA products, and documents sufficient to identify the process by which they were made, including but not limited to batch records, certificates of analysis, and documents sufficient to show whether the samples are representatives.

(D.I. 487.)

As Mylan pointed out in its July 5, 2012, letter to the Court (D.I. 493)—and Shionogi does not dispute—Mylan complied with this request. Shionogi has never said otherwise. Moreover, Shionogi has not suggested (and could not legitimately suggest) that Mylan's response to its Request No. 29 was "incomplete or incorrect." Therefore, Rule 26's duty to supplement is immaterial. Mylan's response to Request No. 29 and its subsequent production were complete and correct, and Mylan, therefore, is under no obligation to supplement its response. *See* Fed. R. Civ. P. 26(e)(1)(A) (requiring supplementation when the responding party learns that its response "is incomplete or incorrect"). Mylan has nevertheless acknowledged the Court's oral Order requiring Lupin to produce the samples requested and has agreed to do the same without the need for a Court order.

Shionogi's position that Mylan is under an obligation to supplement its previous sample production would convert Rule 26's supplementation requirement into a resupply requirement. In other words, in Shionogi's view, Rule 26 requires Mylan to continually reproduce product samples. There is no legal support for Shionogi's position, and Shionogi certainly has cited none. The *AVX Corp. v. Cabot Corp.* decision Shionogi cites dealt only with the timeliness of a supplemental response to an interrogatory regarding damages. *See* 251 F.R.D. 70, 72 (D. Mass.

² Mylan has confirmed that, if the metformin products at issue are manufactured, they will be manufactured in India.

The Honorable Joel Schneider
 July 27, 2012
 Page 3

Morris James LLP

2008) (“Pending before this court is a motion to strike an untimely supplemental answer to a damages interrogatory served . . .”). Furthermore, the supplemental response at issue was served “after the close of fact and expert discovery.” *Id.*

Although *AVX Corp.* is factually inapposite, it is nonetheless instructive. For instance, the court in *AVX Corp.* correctly construed Rule 26(e) to require a party to supplement a previous response “upon learning that it is materially incomplete or incorrect.” *Id.* at 76. Therefore, Shionogi’s own authority undermines Shionogi’s position. In at least this regard, *AVX Corp.* is consistent with holdings from the Districts of both Delaware and New Jersey. *See B. Braun Melsungen AG v. Teramo Med. Corp.*, 749 F. Supp. 2d 210, 221 (D. Del. 2010) (citing Rule 26(e)(1)(A) for the proposition that “[p]arties are always under an obligation to supplement their contentions, including supplementing their expert reports, when it becomes necessary to do so” (emphasis added)); *In re LG Front Load Washing Machine Class Action Litig.*, Civil Action No. 08-51, 2011 U.S. Dist. LEXIS 492, at *7 (D.N.J. Jan. 4, 2011) (noting that the duty to supplement is triggered by knowledge of an “incomplete or incorrect” response).

In short, Shionogi has cited no authority that would support a conclusion that Rule 26’s duty to supplement gives rise to an ongoing duty to resupply Shionogi with samples. Furthermore, Mylan respectfully submits that to construe Rule 26(e) to impose such a duty would render meaningless the rule’s “incomplete or incorrect” limitation. Instead, the responding party would be obliged to produce an indefinite number of samples for an indefinite period of time. Moreover, the duty would be without standards by which to measure compliance. Neither courts nor litigants would be able to determine whether a party had satisfied its resupply obligation.

Even assuming, solely for the sake of argument, that Mylan has a legal obligation to produce the newly requested samples under Rule 26(e)(1), Shionogi’s request for relief from the Court is nonetheless improper. It is tantamount to a prospective motion to compel under Rule 37. Rule 37 does not permit a motion to compel in anticipation (however unreasonable) of a violation of a discovery obligation. It is retrospective in nature and provides for relief only upon, in relevant part, a party’s failure to respond to the request under Rule 34 or improper refusal to produce that which is requested. *See* Fed. R. Civ. P. 37(a)(3)(B); *see also, e.g., Scull v. Mgmt. & Training Corp.*, Civil Action No. 11-0207, 2012 U.S. Dist. LEXIS 91613, at *20-*21 (D.N.M. June 28, 2012) (“According to rule 37, if a party does not respond to an interrogatory or to a request for production, the party requesting discovery may move the Court to compel the opposing party to respond” (emphasis added)); *cf. Robinson v. Potter*, 453 F.3d 990, 995 (8th Cir. 2006) (holding that it was not error to deny a “prospective motion for additional discovery” because such a motion was both “unnecessary . . . and untimely”). Mylan has fully responded to Shionogi’s only Rule 34 request for samples and has produced samples in accordance with that request. Even if a duty to supplement may arise (assuming the duty to supplement is relevant), it has not yet arisen.

Furthermore, the relief Shionogi seeks is a preemptive order compelling Mylan to produce samples within a pre-defined period of time should Mylan decide to manufacture the

The Honorable Joel Schneider
July 27, 2012
Page 4

Morris James LLP

tablets. As Shionogi itself admits, assuming again for the sake of argument that Rule 26(e) governs, Rule 26(e) already requires supplementation in a “timely manner.” Fed. R. Civ. P. 26(e)(1)(a).³ Consequently, to grant Shionogi the relief it seeks would be tantamount to issuing an advisory opinion as to what would constitute a “timely manner” under these circumstances if Mylan were to manufacture additional tablets. Mylan respectfully submits that Shionogi’s request is improper, and the better approach would be for the Court to address any argument Shionogi may make that Mylan has actually failed to comply with its discovery obligations, again assuming Rule 26(e) is even applicable. *See Scull*, 2012 U.S. Dist. LEXIS 91613 at *27 (“Because discovery was not yet due, Scull had no reason to move the Court to compel MTC to produce these documents.”); *Owle v. Cherokee Boys Club*, Civil Action No. 2:10-cv-7, 2010 U.S. Dist. LEXIS 43738, at *4-*5 (W.D.N.C. April 2, 2010) (holding that determining what discovery should be provided prior to the service of requests or a motion to compel would lead to the issuance of “proscribed advisory opinions”); *Walker v. Meyer*, Civil Action No. 08-cv-01911, 2008 U.S. Dist. LEXIS 123147, at *4 (D. Colo. Oct. 30, 2008) (refusing to “issue an advisory opinion regarding the type of discovery to which Plaintiff need not respond”).

Shionogi misapprehends Mylan’s position. Mylan is not seeking a protective order permitting Mylan to wait a certain period of time to produce samples in the event tablets are manufactured.⁴ Rather, Mylan contends that there is no issue to resolve at this time but has agreed nonetheless to produce samples in the event it launches its ANDA products. If Shionogi has reason to believe that Mylan has not complied with its discovery obligations, Shionogi may present its argument to the Court at the appropriate time. Until then, Shionogi is simply wasting the Court’s and Mylan’s resources in raising this issue now.

To the extent that Shionogi contends that this situation is unique because it either needs to test Mylan’s product or seek an injunction, Shionogi fails to explain how this case is different from any other patent infringement case. The idea that a company would inform a patentee in advance of launching an allegedly infringing product is unheard of. Moreover, the Federal Circuit has made it clear that this is not a case for a preliminary injunction. The fact that the Federal Circuit’s recent decision stripping Shionogi of its preliminary injunction did not address the second patent at issue is irrelevant. Shionogi has asserted the very same patents against both

³ Shionogi’s purported distinction between “seasonably amend” and “timely manner” is a distinction without a difference. Rule 26(e) was amended in 2007 to eliminate the “fine distinction” between the obligation to supplement disclosures “at appropriate intervals” and the obligation to “seasonably amend” discovery responses. Fed. R. Civ. P. 26 2007 Amendment advisory committee’s note. The advisory committee prefaced its comments by noting that the change to the language was “intended to be stylistic only.” *Id.*

⁴ Nor does Mylan contend that the duty to supplement—in the limited circumstances where supplementation is required—is contingent upon repeated discovery requests. Therefore, both *Robbins & Myers, Inc. v. J.M. Huber Corp.* and *Adams v. Teck Cominco Alaska, Inc.*, are inapposite. *See Robbins & Myers, Inc.*, 274 F.R.D. 63, 78 (W.D.N.Y. 2011) (holding that duty to supplement was not contingent upon request for supplementation); *Adams*, 231 F.R.D. 578, 580 (D. Ak. 2005) (same).

The Honorable Joel Schneider
July 27, 2012
Page 5

Morris James LLP

Lupin and Mylan, and its decision to seek an injunction against Lupin based on only one of the two patents Shionogi asserted speaks volumes about Shionogi's own view of the likelihood of succeeding on the other patent against either Mylan or Lupin.

The Court correctly recognized that Shionogi's request is little more than a thinly veiled attempt to obtain through the backdoor that which it cannot obtain through the front, namely, advance notice of a product launch. Although Shionogi's motives may be irrelevant to the legal analysis, they nevertheless underscore the impropriety of Shionogi's request.

In conclusion, Mylan respectfully submits that there is no issue for the Court to resolve at this time. Although Mylan has agreed to produce additional samples upon launching its product, Mylan is under no obligation to supplement its previous production under Rule 26(e). In any event, Shionogi's request for relief is premature, and the preemptive, contingent relief it seeks is improper. Therefore, Mylan respectfully requests that Shionogi's request be denied.

We would be happy to answer any questions the Court may have. We appreciate the Court's consideration of this matter.

Respectfully,

/s/ Mary B. Matterer

Mary B. Matterer (I.D. # 2696)
mmatterer@morrisjames.com

cc: Counsel of record (via email)